OCT 11 2000

510 (k) Summary K002690

SUBMITTER:	**Nonin Medical, Inc.**
Address:	**Nonin Medical, Inc.** **2605 Fernbrook Lane North** **Plymouth, MN 55447-4755**
Telephone:	**612.553.9968**
CONTACT PERSON:	**Richard P. Bennett, Director of Regulatory Affairs**
DATE PREPARED:	**October 6, 2000,**
TRADE NAME:	**Nonin® PalmSAT ®, Model 2500, Pulse Oximeter with 2500C & 2500B**
COMMON NAME:	**Pulse Oximeter with Charging stand and NiMH battery pack**

SUBSTANTIALLY EQUIVALENT TO:

The Nonin, Model 2500 Hand Held Pulse Oximeter

DESCRIPTION OF THE DEVICE:

The Model 2500 Pulse Oximeter determines arterial hemoglobin saturation (%SpO2) by measuring absorption of red and infrared (IR) light passed through the tissue. The Model 2500C allows the Model 2500 to be recharged when connected the appropriate power supply. The charger stand can fully recharge the NiMH batteries in about 90 minutes.

INDICATIONS FOR USE:

The Nonin Model 2500 Hand Held Pulse Oximeter is intended to be used for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients in hospitals, ambulatory, home, and EMS (emergency medical service) environments. The Model 2500 is intended for spot checking and/or continuous monitoring when attended by a trained health care professional. The Model 2500C allows the Model 2500 to be recharged when connected to the appropriate power supply. The charger stand can fully recharge the Model 2500B (NiMH batteries) in about 90 minutes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2000

Mr. Richard P. Bennett
Nonin Medical, Inc.
2605 Fernbrook Lane North
Plymouth, MN 55447-4755

Re: K002690
Model 2500 Hand Held Pulse Oximeter with Model 2500C Charging Stand and Model 2500B NiMH Battery Pack
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: September 28, 2000
Received: October 2, 2000

Dear Mr. Bennett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number:

K0002690

Device Name:

Model 2500 Hand Held Pulse Oximeter with Model 2500C charging stand and Model 2500B NiMH battery pack

Indications for Use:

The Nonin Model 2500 Hand Held Pulse Oximeter is intended to be used for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients in hospitals, ambulatory, home, and EMS (emergency medical service) environments. The Model 2500 is intended for spot checking and/or continuous monitoring when attended by a trained health care professional. The Model 2500C allows the Model 2500 to be recharged when connected to the appropriate power supply. The charger stand can fully recharge the Model 2500B (NiMH batteries) in about 90 minutes.

Division of Cardiovascular & Respiratory Devices
510(k) Number K002690

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____